Venue Laboratories, Inc., 270 Northfield Rd., P.O. Box 46568, Bedford, OH 44146, has filed an application requesting approval for the export of the human drug PrVerapamil Injection, U.S.P. 2.5 mg/mL, 2 mL vial, and 4 mL vial to Canada. PrVerapamil Injection, U.S.P. 2.5 mg/mL, 2 mL vial, and 4 mL vial is indicated for the rapid conversion to sinus rhythm of paroxysmal supraventricular tachycardias. When clinically advisable, appropriate vagal maneuvers should be attempted prior to PrVerapamil Injection administration. The application was received and filed in the Center for Drug Evaluation and Research on April 22, 1994, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 23, 1994, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: May 3, 1994.

Stephanie R. Gray,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 94-11440 Filed 5-10-94; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 93E-0268]

Determination of Regulatory Review Period for Purposes of Patent Extension; Reality™ Female Condom

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for the Reality™ Female Condom and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved the Reality™ Female Condom for marketing. The Reality™ Female Condom is a medical device that is indicated for use to help prevent pregnancy and sexually transmitted diseases, including the human immunodeficiency virus (HIV) infection, during vaginal intercourse. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for the Reality™ Female Condom (U.S. Patent No. 4,976,273) from Chartex International Plc; the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 28, 1993, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period, and the approval of the Reality™ Female Condom represented the first commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for the Reality™ Female Condom is 2,017 days. Of this time, 1,460 days occurred during the testing phase of the regulatory review period, while 557 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date the first clinical trial on this device was begun*: October 31, 1987. The clinical trial cited by the applicant was conducted outside the United States and was not subject to FDA's requirement for an investigational device exemption (IDE) under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) nor FDA's requirement for an institutional review board (IRB) approval under section 520(g)(3) of the act. Therefore, the testing phase begins on the date the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device (21 CFR 60.22(c)(1)(iii)). The applicant has stated that the date on which the device was first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device was October 31, 1987. Because of the circumstances previously described for the clinical trial cited by the applicant, FDA has no record in which to review this date (21 CFR 60.20(c)(6). Although FDA cannot, therefore, confirm that testing began as stated by the applicant, FDA is using this date as the start of the testing phase.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act*: October 29, 1991. FDA has verified the applicant's claim that the premarket approval application (PMA) for the Reality™ Female Condom (PMA P910064) was initially submitted on October 29, 1991.

3. *The date the application was approved*: May 7, 1993. FDA has

verified the applicant's claim that PMA P910064 was approved on May 7, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 717 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 11, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 7, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 29, 1994.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 94–11439 Filed 5–10–94; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 1994.

Name: National Advisory Council on the National Health Service Corps.

Date and Time: June 3–5, 1994.

Place: Radisson Hotel Newark Airport, 128 Frontage Road, Newark, New Jersey 07114, (201) 690–5500. The meeting is open to the public.

Purpose: The Council will advise and make appropriate recommendations on the National Health Service Corps (NHSC) program as mandated by legislation. It will also review and comment on proposed regulations promulgated by the Secretary under provision of the legislation.

Agenda: The meeting will begin on Friday, June 3, at 8:30 a.m. with site visits to health care facilities in New Jersey and New York City. The agenda for the business meetings on Saturday and Sunday, June 4–5, will include updates on the Bureau of Primary Health Care, the National Health Service Corps, presentations by New York public health officials, universal service, and mental and dental health issues.

The meeting is open to the public, however, no transportation will be provided for the site visits.

Anyone requiring information regarding the subject Council should contact Ms. Nada Schnabel, National Advisory Council on the National Health Service Corps, 8th floor, 4350 East West Highway, Rockville, Maryland 20857, Telephone (301) 594–4136.

Agenda items are subject to change as priorities dictate.

Dated: May 6, 1994.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 94–11363 Filed 5–10–94; 8:45 am]

BILLING CODE 4160–15–P

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory bodies scheduled to meet during the month of June 1994:

Name: National Advisory Committee on Rural Health.

Date and Time: June 13–15, 1994; 1:30 p.m.

Place: The Des Moines Marriott, 700 Grand Avenue, Des Moines, IA 50309, (515) 235–5500. The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary with respect to the delivery, financing, research, development and administration of health care services in rural areas.

Agenda: Plenary session on Monday, June 13, will be devoted to "The Health Care Reform in Rural Areas and Telemedicine." Other plenary topics will include discussions and presentations on the changes on farm safety, rural physician recruitment and placement, and a rural community empowerment project, "Hometown Health." In addition, a presentation regarding the application of the field of telemedicine in Health Care Reform will be provided at the Iowa Methodist Medical Center. A trip to the Farm Bureau has been planned for Monday evening. The presentation will cover the Bureau's Farm Safety Program.

The Education and Health Services Work Group and the Health Care Financing Work Group will meet between plenary sessions on developing recommendations and strategies for improving health services delivery in rural areas.

The meeting will adjourn on Wednesday, June 15, at noon. (Transportation on field trips will not be provided. All sessions are open to the public.)

Anyone requiring information regarding the subject Council should contact Jeffery Human, Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Ms. Arlene Granderson, Director of Operations, Office of Rural Health Policy, Health Resources and Services Administration, Telephone (301) 443–0835.

Name: National Commission on Allied Health

Date and Time: June 20–21, 1994, 8:30 a.m.

Place: Stouffer Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036. The meeting is open to the public.

Purpose: The National Commission on Allied Health shall: (1) Make recommendations to the Secretary of Health and Human Services, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives, with respect to: (A) The supply and distribution of allied health personnel throughout the United States; (B) current and future shortages or excesses of allied health personnel, particularly in medically underserved and rural communities; (C) priority research needs within the allied health professions; (D) appropriate Federal policies relating to the matters described in subparagraphs (A) through (C), including policies concerning changes in the financing of undergraduate and graduate allied health programs, changes in the types of allied health education, and the appropriate Federal role in the development of a research base in the allied health professions; (E) appropriate efforts to be carried out by health care facilities, schools and programs of allied health, and professional associations with respect to the matter referred to in subparagraph (A), including efforts for changes in undergraduate and graduate allied health education programs, and private support for research initiatives; (F) deficiencies and needs for improvements in existing data bases concerning the supply and distribution of training programs for allied health in the United States and steps that should be taken to eliminate such deficiencies; and (G) problems, and recommendations for the resolution of such problems, relating to the roles and functions of professionals within the allied health fields and other fields such as medicine and dentistry; and (2) encourage entities providing allied health education to conduct activities to voluntarily achieve the recommendations of the Commission.

Agenda: The agenda includes Opening and Welcome remarks; Introduction of members; Congressional perspective of the Commission; Public Advisory Committee Overview; Election of the Chairperson; development of subcommittees; presentations on supply and distribution, shortages and excess and current research activities.

Anyone requiring information regarding the Committee should contact Mr. Neil H.